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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,307	04/02/2001	Richard KroczeK	7853-235-999	8614

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,307	Applicant(s) KROCZEK, RICHARD	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21,25-28,30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21,25-28,30 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in ^{09/509,283, a} ~~this~~ National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Changes

1. Applicant's amendment, filed 8/19/02 (Paper No. 14), is acknowledged.
Claims 22-24, 29, 31 and 36 have been canceled. Claims 1-20 have been canceled previously.
Claims 21, 25-28, 30 and 32-35 have been amended.
Claims 21, 25-28, 30 and 32-35 are pending.
2. Applicant's election without traverse of Group IV in Paper No. 14 is acknowledged.

Sequence Compliance

3. Sequence compliance: Applicant's provision of a third CRF, Sequence Listing, and Statement that the contents are identical on 8/19/02 (Paper No. 11), is acknowledged. The CRF has been found acceptable and entered.

Drawings

4. The formal drawings submitted 8/19/02 have been approved by the Draftsman.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Copies of the certified copies have been filed in parent Application No. 09/509,283, filed on March 22, 2000 which is a national stage filing of PCT/DE98/02896, filed September 23, 1998.

Specification

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Objections

7. Claim 21 is objected to because of the following informalities: it appears that the last line should recite -- inhibited -- rather than "modulated". Appropriate correction is required.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21, 25-28, 30 and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, 25-28, 30 and 33-35 are ambiguous in that they recite methods requiring a monoclonal antibody to a human polypeptide that is not distinctly claimed. The term "8F4 polypeptide" identifies the polypeptide bound by the monoclonal antibody only by an arbitrary protein name, "8F4". Even though some properties of the polypeptide are recited in the claims, these properties are too general to clearly distinguish the "8F4 polypeptide" from other polypeptides because neither an amino acid sequence nor a deposited antibody is used to clearly identify the genus of polypeptides that are "8F4" polypeptides.

Applicant should particularly point out and distinctly claim an "8F4 polypeptide" recognized by the antibodies of the instant methods by providing a reference amino acid sequence, or by identifying the polypeptide as a polypeptide recognized by a deposited antibody.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 112 first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Applicant's provision on October 4, 2001 of a copy of a Declaration under 37 CFR 1.132 by Dr. Kroczeck, filed in a related continuation application (USSN unassigned at time of filing) of parent application USSN 09/509,283 is acknowledged.

12. Applicant's comments are also acknowledged regarding the following post-filing date references:
Ozkaynak et al. Nature Immunol. July 2001; 2(7):591-596;
Gonzalo et al. Nature Immunol. July 2001; 2(7):597-604;
Wills-Karp M., Immunopharmacol. 2000; 48:263-268;
Keane-Myers et al, J. Immunol. January 15 1998 ; 160 :1036-1043; and
Mathur et al., Am. J. Respir. Cell Mol. Biol. 1999; 21:498-509.

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13. Claims 21, 25-28, 30 and 33-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of inhibiting costimulation of human T lymphocytes and a method of inhibiting rejection of an organ transplant in which a monoclonal antibody is administered/contacted *that binds the 8F4 polypeptide set forth in SEQ ID NO:2*, or

a method of inhibiting costimulation of human T lymphocytes and a method of inhibiting rejection of an organ transplant in which a monoclonal antibody is administered/contacted that binds *an 8F4 polypeptide recognized by the (deposited) 8F4 monoclonal antibody* disclosed in the specification (e.g., pages 11-12);

does not reasonably provide enablement for these methods comprising administering/contacting with a monoclonal antibody to any "human 8F4 polypeptide" as currently recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The instant claims encompass the use of antibodies to a genus of polypeptides encompassed by the term "8F4 polypeptide" and having the general characteristics recited. However, there is insufficient guidance in the specification such that one skilled in the art could practice the invention as broadly claimed.

The specification discloses the 8F4 antibody which recognizes a human "8F4 antigen" that is an inducible T cell costimulatory molecule, occurs on two-signal activated T cells, and is a 55-60 kDa dimeric polypeptide composed of 27 kDa and 29 kDa subunits. However, the instant claims encompass methods employing any antibody that binds any "8F4" polypeptide that has the general characteristics recited.

In the absence of a defined amino acid sequence or a repeatable means of isolating an 8F4 polypeptide, it would be highly unpredictable that the skilled artisan could make antibodies that could be used in the instant methods. There is no requirement that the 8F4 polypeptide recited have any particular sequence which could be used as a basis for synthesizing 8F4 polypeptides for the production of antibodies for use in the instant methods. Neither can a skilled artisan without undue experimentation isolate a polypeptide which is an 8F4 polypeptide and use it to produce antibodies for use in the instant method unless the claims require that the polypeptide is one recognized by the 8F4 antibody disclosed in the specification and the 8F4 antibody is made readily available to the public (i.e., deposited in compliance with 37 CFR 1.801-1.809). Further, 8F4 polypeptides as broadly recited (i.e., those sharing only the general characteristics recited without necessarily sharing amino acid sequence homology or recognition by the 8F4 antibody) would not be expected to share the functions of the particular 8F4 polypeptide disclosed in the specification. Therefore, it would be unpredictable that antibodies to these other polypeptides, although they meet the instantly recited general limitations, would function in the instant methods.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance establishing a structural basis that would clearly permit the skilled artisan to make (synthesize or isolate) a human 8F4 polypeptide, it would require undue experimentation to make antibodies to any human 8F4 polypeptide. Therefore, it would require undue experimentation to practice the instant methods as broadly claimed and the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

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It is suggested that Applicant limit the claims by reciting that the 8F4 polypeptide is the polypeptide set forth in SEQ ID NO:2; or by reciting that the 8F4 polypeptide is recognized by the 8F4 antibody.

Applicant is reminded that if the claims are amended to recited that the 8F4 polypeptide is that recognized by the 8F4 antibody, then the 8F4 antibody and hybridoma would be required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, Applicant is required to assure that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications (see 37 CFR 1.808 (a)(2) and MPEP 2410-2410.01).

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is also required. As an additional means for completing the record, Applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, Applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state that the biological material which is deposited is the biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See 37 CFR 1.804(b) and MPEP 2406.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
October 30, 2002

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